

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED,	x	
	x	
	x	
Plaintiff,	x	Civil Action No. 04-171-KAJ
	x	
v.	x	
	x	
TEVA PHARMACEUTICALS USA, INC. and	x	
TEVA PHARMACEUTICAL INDUSTRIES	x	
LIMITED,	x	
	x	
Defendants.	x	
	x	

DEFENDANTS' FIRST SET OF REQUESTS FOR ADMISSION

Defendants, by and through its attorneys and pursuant to Rule 36 of the Federal Rules of Civil Procedure, hereby requests that Plaintiff Glaxo Group Limited answer the following requests for admission within thirty (30) days.

Terms and Definitions

The following definitions shall apply to these requests:

“Document” means any document within the scope of the Federal Rules of Civil Procedure, including, but not limited to, any writings, drawings, graphs, charts, photographs, and any other data compilations from which information can be obtained and translated, if necessary. This includes all information in paper, electronic, or computer readable formats.

“Glaxo” means Plaintiff Glaxo Group, Ltd. including any parent, subsidiary, affiliate, division, partner, joint venturer, agent, apparent agent, officer, shareholder, employee, servant, predecessor, or successor thereof.

“Glaxo pharmaceutical research and development” means activities, information and documents relating to the research, development, investigation, manufacture and sale of pharmaceutical products, including, but not limited to, the identification of new pharmaceutical products, the formulation of pharmaceutical products, the modification and formulation of existing pharmaceutical products, the collection and analysis of data or information for any regulatory purpose, either in the United States or abroad, the submission of data or information for any regulatory purpose, either in the United States or abroad, and internal correspondence, notes, and other documents within the scope of the Federal Rules of Civil Procedure relating to any of the aforementioned purposes.

“*Glaxo v. Pharmadyne*” means the litigation reported at 32 F. Supp. 2d 265, civil number AMD 96-455.

“Litigation” means any proceeding before a court or administrative agency inside or outside the United States or any of its territories, including lawsuits, arbitrations, mediations, and any other proceeding in which the rights of the parties are in dispute.

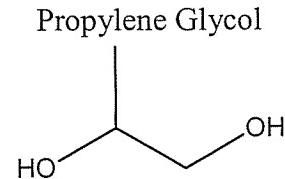
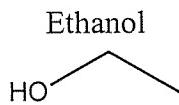
“Dr. Long” means David R. Long, the sole inventor of U.S. Pat. No. 5,068,249.

“Person” means any natural person, corporation, partnership, joint venture, sole proprietorship, or any other business entity.

REQUESTS FOR ADMISSION

REQUEST NO. 1: Admit that Glaxo regularly conducts pharmaceutical research and development.

REQUEST NO. 2: Admit that the drawing below depicts the molecular structures of ethanol and propylene glycol.



REQUEST NO. 3: Admit that the drawings on G027447 accurately depict the molecular structures of ethanol, glycerol and propylene glycol.

REQUEST NO. 4: Admit that propylene glycol is an alcohol.

REQUEST NO. 5: Admit that propylene glycol is an aliphatic alcohol.

REQUEST NO. 6: Admit that propylene glycol is a lower aliphatic alcohol.

REQUEST NO. 7: Admit that 1,2-propanediol is a chemical nomenclature that is synonymous to propylene glycol.

REQUEST NO. 8: Admit that at 25°C, more than twice the amount of methyl *p*-hydroxy-benzoate is soluble in 100 grams of ethanol than in an equal amount of propylene glycol as shown on document number G035271.

REQUEST NO. 9: Admit that at 25°C, more than twice the amount of ethyl *p*-hydroxy-benzoate is soluble in 100 grams of ethanol than in an equal amount of propylene glycol as shown on document number G035271.

REQUEST NO. 10: Admit that at 25°C, more than three times the amount of *n*-propyl *p*-hydroxy-benzoate is soluble in 100 grams of ethanol than in an equal amount of propylene glycol as shown on document number G035271.

REQUEST NO. 11: Admit that at 25°C, almost twice the amount of butyl *p*-hydroxy-benzoate is soluble in 100 grams of ethanol than in an equal amount of propylene glycol as shown on document number G035271.

REQUEST NO. 12: Admit that at 25°C, more than five times the amount of benzyl *p*-hydroxy-benzoate is soluble in 100 grams of ethanol than in an equal amount of propylene glycol as shown on document number G035271.

REQUEST NO. 13: Admit that Glaxo investigated the use of propylene glycol in an oral liquid ranitidine formulation on or around November 19, 1984 as shown on document number G013492.

REQUEST NO. 14: Admit that Glaxo investigated the use of 2.5% w/v propylene glycol for enhanced preserving power in a ranitidine syrup formulation in June 1985 as shown on document numbers G026730-31.

REQUEST NO. 15: Admit that 2.5% w/v propylene glycol failed to arrest the growth of pseudomonas cepacia in Zantac syrup.

REQUEST NO. 16: Admit that documents numbered G032499 – G032505 are a genuine copy of U.S. Pat. No. 4,521,431.

REQUEST NO. 17: Admit that U.S. Pat. No. 4,521,431 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 18: Admit that documents numbered G032499 – G032505 are admissible.

REQUEST NO. 19: Admit that documents numbered G032506 – G032524 are a genuine copy of U.S. Pat. No. 4,128,658.

REQUEST NO. 20: Admit that U.S. Pat. No. 4,128,658 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 21: Admit that documents numbered G032506 – G032524 are admissible.

REQUEST NO. 22: Admit that U.S. Patent No. 4,567,178 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 23: Admit that a certified copy of U.S. Patent No. 4,567,178 is admissible.

REQUEST NO. 24: Admit that U.S. Patent No. 5,068,249 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 25: Admit that a genuine copy of U.S. Patent No. 5,068,249 is admissible.

REQUEST NO. 26: Admit that Glaxo received written notice of Teva's ANDA No. 76-937 on February 5, 2004.

REQUEST NO. 27: Admit that Teva's written notice alleged that the '249 patent is invalid, unenforceable or not infringed by Teva's proposed product submitted under ANDA No. 76-937.

REQUEST NO. 28: Admit that documents numbered G000236 – G000308 and G026056 – G026127 are genuine copies of the file wrapper for U.S. Patent Application No. 07/131,442.

REQUEST NO. 29: Admit that the file wrapper for U.S. Patent Application No. 07/131,442 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 30: Admit that documents numbered G000236 – G000308 and G026056 – G026127 are admissible.

REQUEST NO. 31: Admit that documents numbered G027097 – G027206 are genuine copies of the file wrappers for U.S. Patent Application Nos. 07/344,620 and 07/494,804.

REQUEST NO. 32: Admit that the file wrappers for U.S. Patent Application Nos. 07/344,620 and 07/494,804 are public records pursuant to Fed. R. Evid. 803.

REQUEST NO. 33: Admit that documents numbered G027097 – G027206 are admissible.

REQUEST NO. 34: Admit that documents numbered G032375 – G032498 are a genuine copy of the file wrapper for U.S. Patent Application No. 07/344,620.

REQUEST NO. 35: Admit that the file wrapper for U.S. Patent Application No. 07/344,620 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 36: Admit that documents numbered G032375 – G032498 are admissible.

REQUEST NO. 37: Admit that documents numbered G032269 – G032374 are a genuine copy of the file wrapper for U.S. Patent No. 5,068,249.

REQUEST NO. 38: Admit that the file wrapper for U.S. Patent No. 5,068,249 is a public record pursuant to Fed. R. Evid. 803.

REQUEST NO. 39: Admit that documents numbered G032269 – G032374 are admissible.

REQUEST NO. 40: Admit that documents numbered G027547 – G027640 are genuine copies of a portion of the trial transcript in the *Glaxo v. Pharmadyne* case, Civ. Nos. AMD-96-455 and AMD-96-1853.

REQUEST NO. 41: Admit that documents numbered G027547 – G027640 are genuine copies of documents that are public records pursuant to Fed. R. Evid. 803.

REQUEST NO. 42: Admit that documents numbered G027547 – G027640 are admissible.

REQUEST NO. 43: Admit that documents numbered G027641 – G027776 are genuine copies of a portion of the trial transcript in the *Glaxo v. Pharmadyne* case, Civ. Nos. AMD-96-455 and AMD-96-1853.

REQUEST NO. 44: Admit that documents numbered G027641 – G027776 are genuine copies of documents that are public records pursuant to Fed. R. Evid. 803.

REQUEST NO. 45: Admit that documents numbered G027641 – G027776 are admissible.

REQUEST NO. 46: Admit that documents numbered G026714 – G026879 are genuine copies of Glaxo pharmaceutical research documents.

REQUEST NO. 47: Admit that G026714 – G026879 are copies of the original documents.

REQUEST NO. 48: Admit that any statements made in documents numbered G026714 – G026879 were made by a person authorized by Glaxo to make the statement.

REQUEST NO. 49: Admit that any statements made in documents numbered G026714 – G026879 were made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 50: Admit that documents numbered G026714 – G026879 are Glaxo records kept in the course of its regularly conducted pharmaceutical research and development and it was the regular practice of Glaxo's pharmaceutical research and development to make the aforementioned documents.

REQUEST NO. 51: Admit that G026714 – G026879 are business records under Fed. R. Evid. 803(6).

REQUEST NO. 52: Admit that any statements made in documents numbered G026932 – G026954 were made by a person authorized by Glaxo to make the statement.

REQUEST NO. 53: Admit that any statements made in documents numbered G026932 – G026954 were made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 54: Admit that documents numbered G026932 – G026954 are Glaxo records kept in the course of its regularly conducted pharmaceutical research and development and it was the regular practice of pharmaceutical research and development to make the aforementioned documents.

REQUEST NO. 55: Admit that G026932 – G026954 are business records under Fed. R. Evid. 803(6).

REQUEST NO. 56: Admit that documents numbered G027092 – G027093 are genuine copies of Glaxo pharmaceutical research and development documents.

REQUEST NO. 57: Admit that G027092 – G027093 are copies of the original documents.

REQUEST NO. 58: Admit that any statements made in documents numbered G027092 – G027093 were made by a person authorized by Glaxo to make the statement.

REQUEST NO. 59: Admit that any statements made in documents numbered G027092 – G027093 were made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 60: Admit that documents numbered G027092 – G027093 are Glaxo records kept in the course of its regularly conducted pharmaceutical research and development and it was the regular practice of Glaxo's pharmaceutical research and development to make the aforementioned documents.

REQUEST NO. 61: Admit that G027092 – G027093 are business records under Fed. R. Evid. 803(6).

REQUEST NO. 62: Admit that documents numbered G027026 – G027027 are genuine copies of Glaxo pharmaceutical research and development documents.

REQUEST NO. 63: Admit that G027026 – G027027 are copies of the original documents.

REQUEST NO. 64: Admit that any statements made in documents numbered G027026 – G027027 were made by a person authorized by Glaxo to make the statement.

REQUEST NO. 65: Admit that any statements made in documents numbered G027026 – G027027 were made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 66: Admit that documents numbered G027026 – G027027 are Glaxo records kept in the course of its regularly conducted pharmaceutical research and development and it was the regular practice of Glaxo's pharmaceutical research and development to make the aforementioned documents.

REQUEST NO. 67: Admit that G027026 – G027027 are business records under Fed. R. Evid. 803(6).

REQUEST NO. 68: Admit that documents numbered G027328 – G027346 are genuine copies of Glaxo pharmaceutical research and development documents.

REQUEST NO. 69: Admit that G027328 – G027346 are copies of the original documents.

REQUEST NO. 70: Admit that any statements made in documents numbered G027328 – G027346 were made by a person authorized by Glaxo to make the statement.

REQUEST NO. 71: Admit that any statements made in documents numbered G027328 – G027346 were made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 72: Admit that documents numbered G027328 – G027346 are Glaxo records kept in the course of its regularly conducted pharmaceutical research and development and it was the regular practice of Glaxo's pharmaceutical research and development to make the aforementioned documents.

REQUEST NO. 73: Admit that G027328 – G027346 are business records under Fed. R. Evid. 803(6).

REQUEST NO. 74: Admit that document number G028639 is a genuine copy of a writing by Dr. John Hempenstall.

REQUEST NO. 75: Admit that G028639 is an authentic copy of the original document.

REQUEST NO. 76: Admit that any statements made in document number G028639 was made by a person authorized by Glaxo to make the statement.

REQUEST NO. 77: Admit that any statements made in document number G028639 was made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 78: Admit that documents numbered G028640 – G028644 are genuine copies of Glaxo pharmaceutical research and development documents.

REQUEST NO. 79: Admit that G028640 – G028644 are copies of the original documents.

REQUEST NO. 80: Admit that any statements made in documents numbered G028640 – G028644 were made by a person authorized by Glaxo to make the statement.

REQUEST NO. 81: Admit that any statements made in documents numbered G028640 – G028644 were made by a Glaxo employee at the time the statement was made concerning a matter within the scope of the employee's employment.

REQUEST NO. 82: Admit that documents numbered G028640 – G028644 are Glaxo records kept in the course of its regularly conducted pharmaceutical research and development and it was the regular practice of Glaxo's pharmaceutical research and development to make the aforementioned documents.

REQUEST NO. 83: Admit that neither Glaxo nor Dr. Long submitted the Sunderland and Watts article shown at document numbers G017299 – G017313 for consideration by the U.S. Patent and Trademark Office during the prosecution of the patent applications that issued as U.S. Patent No. 5,068,249.

REQUEST NO. 84: Admit that neither Glaxo nor Dr. Long submitted U.S. Patent No. 4,567,178 for consideration by the U.S. Patent and Trademark Office during the prosecution of the patent applications that issued as U.S. Patent No. 5,068,249.

REQUEST NO. 85: Admit that Teva's accused ranitidine formulation does not contain a "stabilizing effective amount of ethanol" as claimed in claims 1 through 10 of U.S. Patent No. 5,068,249.

REQUEST NO. 86: Admit that Teva's accused ranitidine formulation does not contain a "7% to 8% weight/volume ethanol based on the complete formulation" as claimed in claims 11 and 12 of U.S. Patent No. 5,068,249.

REQUEST NO. 87: Admit that Teva's accused ranitidine formulation does not literally infringe any claim of U.S. Patent No. 5,068,249.

REQUEST NO. 88: Admit that the original formulation for Glaxo's oral ranitidine syrup was based on an earlier Zantac® product for injectable use as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 277.

REQUEST NO. 89: Admit that in November 1983, Glaxo submitted to the U.S. Food and Drug Administration ("FDA") a Notice of Claimed Investigational Exemption for a New Drug for Zantac® (ranitidine hydrochloride) Syrup as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 277.

REQUEST NO. 90: Admit that the original formulation for Zantac® syrup included a preservative system composed of three parabens: methylparaben, propylparaben and butylparaben, but it did not contain any alcohol, and that Dr. Long noticed there was a decrease in the concentration of one of the parabens as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 91: Admit that Dr. Long was surprised at this decrease because there was data from a study of the formulation in sealed bottles showing there was little

change in the product over a two year period as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 92: Admit that the degradation of the paraben concentration did not fit any known law of degradation of parabens as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 93: Admit that Dr. Long had the product analyzed by Glaxo microbiologists who discovered that it contained a microbial named *pseudomonas cepacia* as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 94: Admit that to combat the contamination problem, Dr. Long devised a strategy that included the exploration of the use of ethanol, chlorhexidine, phenoxyethanol, benzalkonium chloride, and propylene glycol as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 95: Admit that in early October 1985, Dr. Long tested the effects of a little less than 1%, 3% and a little over 5% ethanol in the formulation to see if it killed the *pseudomonas cepacia* contaminant as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 96: Admit that Dr. Long felt comfortable using ethanol because it was contained in a similar product on the market, Tagamet, as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 97: Admit that Dr. Long discovered that adding ethanol to the formulation killed the *pseudomonas cepacia* as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 98: Admit that because 5% ethanol was successful in killing the *pseudomonas cepacia*, Dr. Long decided to use 7.5% ethanol (weight/volume) to ensure that a minimum of 5% ethanol (weight/volume) would remain in the product throughout its assigned shelf-life as reported in *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 at 278.

REQUEST NO. 99: Admit that Dr. Long resides out of the United States.

REQUEST NO. 100: Admit that the deposition testimony of Dr. Long taken on February 6, 1997 in the *Glaxo v. Pharmadyne* case is relevant to Glaxo's patent infringement claims against Teva in this case.

REQUEST NO. 101: Admit that Dr. Long's statements in his February 6, 1997 deposition are admissible in this case pursuant to the provisions of Fed. R. Civ. P. 32(a) and Fed. R. Evid. 801(d)(2).

REQUEST NO. 102: Admit that Dr. John Hempenstall, the author of the declaration submitted during the prosecution of the patent application that issued as the '249 patent, resides out of the United States.

REQUEST NO. 103: Admit that the deposition testimony of Dr. John Hempenstall taken on February 28, 1997 in the *Glaxo v. Pharmadyne* case is relevant to Glaxo's patent infringement claims against Teva in this case.

REQUEST NO. 104: Admit that Dr. John Hempenstall's statements in his February 29, 1997 deposition are admissible in this case pursuant to the provisions of Fed. R. Civ. P. 32(a) and Fed. R. Evid. 801(d)(2).

REQUEST NO. 105: Admit that Gillian Amphlett resides out of the United States.

REQUEST NO. 106: Admit that the deposition testimony of Gillian Amphlett taken on April 9, 1997 in the *Glaxo v. Pharmadyne* case is relevant to Glaxo's patent infringement claims against Teva in this case.

REQUEST NO. 107: Admit that Gillian Amphlett's statements in her April 9, 1997 deposition are admissible in this case pursuant to the provisions of Fed. R. Civ. P. 32(a) and Fed. R. Evid. 801(d)(2).

REQUEST NO. 108: Admit that U.S. Pat. No. 4,128,658 has expired.

REQUEST NO. 109: Admit the claims of U.S. Pat. No. 4,128,658 were not enforceable on or after December 9, 2003.

REQUEST NO. 110: Admit that U.S. Pat. No. 4,521,431 has expired.

REQUEST NO. 111: Admit the claims of U.S. Pat. No. 4,521,431 were not enforceable on or after December 9, 2003.

REQUEST NO. 112: Admit that U.S. Pat. No. 4,672,133 has expired.

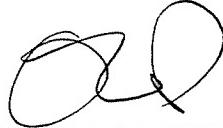
REQUEST NO. 113: Admit the claims of U.S. Pat. No. 4,672,133 were not enforceable on or after December 9, 2003.

REQUEST NO. 114: Admit that U.S. Pat. No. 4,585,790 has expired.

REQUEST NO. 115: Admit the claims of U.S. Pat. No. 4,585,790 were not enforceable on or after December 9, 2003.

Dated: February 10, 2006

By: _____



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CERTIFICATE OF SERVICE

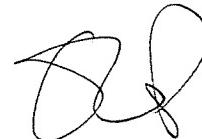
I, Adam W. Poff, Esquire, hereby certify that on February 10, 2005, I caused copies of the foregoing document to be served upon the following counsel of record:

BY HAND

Francis DiGiovanni Esquire
Connolly Bove Lodge & Hutz LLP
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1007 North Orange Street
Wilmington, DE 19801

BY E-MAIL

Brian P. Murphy, Esquire
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Adam W. Poff (#3990)